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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,502	12/17/2001	Kelly Moran	BJA219A	4304

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EXAMINER	
SCHAETZLE, KENNEDY	
ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,502	MORAN, KELLY	
	Examiner	Art Unit	
	Kennedy Schaetzle	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,9,10,12 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,9,10,12 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 2, 4, 12, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff (Pat. No. 4,287,554).

Regarding claim 1, Wolff discloses that the electromagnetic radiation produced by his device may be employed to treat acne, psoriasis, or other skin related disorders. Wolff further discloses that wavelengths within the range from 193 nm to 10.6 micrometers are most effective in treating psoriasis, acne and other skin irregularities or diseases (col. 1, lines 49-57).

While the system of Wolff does not disclose the use of coherent radiation applied with at least one optical fiber, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to utilize such an arrangement because the applicant has not disclosed that coherent light applied with an optical fiber provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with non-coherent light applied by a lamp because, the applicant admits that such light is effective in treating wounds of the type covered by the invention (see page 6, lines 7, 8 and 22-25). The healing process is clearly not dependent upon the particular means used to transmit the radiation to the wound – rather the energy content, wavelength and treatment time. Any artisan looking to direct the radiation to a specific limited affected area of the body would have therefore considered the use of coherent laser radiation as a matter of obvious design. See *Ex parte Clapp*, 224 USPQ 972, 973 (Bd. Pat. App. & Int. 1985), *In re Soli*, 317, F. 2d 941, 947, 137 USPQ 797, 801 (CCPA 1963) and MPEP §2144.02.

As for the treatment of stage 1-2 wounds, please refer to the arguments presented in the prior Office Action under par. 8.

Regarding claim 2, the examiner considers the power density of the Wolff device to be at least 1 W/cm^2 given the effects produced by the application of radiation energy. Since Wolff discloses that skin disorders such as acne and psoriasis may be effectively treated, the power density must be of a sufficient magnitude in order for any beneficial results to occur. Such a magnitude would necessarily be of a similar strength to the applicant's device since it also treats the same conditions by electromagnetic radiation of a similar wavelength. Concerning the exposure times, Wolff discloses that treatment times may correspond to the performance of mundane acts such as brushing ones teeth or combing one's hair. The examiner considers such acts to reasonably fall within the 1 second to 3 minute exposure time.

Regarding claim 12, the examiner considers the radiation produced by the Wolff device to be inherently capable of eradicating bacteria and viral bodies.

Regarding claim 15, similar comments made in the rejection of claim 1 apply here as well. Concerning the use of radiation with a wavelength of 930 nm, those of ordinary skill in the art would have considered the exact wavelength of operation to be an application dependent parameter. The particular ailment being treated and the condition of the patient would necessarily dictate the most appropriate wavelength for the situation at hand, with routine experimentation determining the most effective treatment wavelengths for any given disease and patient type. The applicant further gives no criticality to the use of 930 nm radiation. The applicant has not disclosed that 930 nm radiation provides an advantage, is used for a particular purpose, or solves a stated problem. The applicant to the contrary discloses that wavelengths in the range disclosed by Wolff are effective in treating wounds. One would therefore expect the invention to work equally well within the range of wavelengths disclosed.

3. Claims 1, 2, 4, 12, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehurst (Pat. No. 6,461,866).

Whitehurst discloses the use of a non-coherent, non-ablative light source useful in the cosmetic treatment of dermatological conditions such as portwine stains,

psoriasis, etc. (col. 3, lines 32-46) with an output intensity of generally greater than 1 W/cm^2 (col. 1, lines 65-67), which can be focused and delivered via at least one optical fiber (col. 2, lines 4-7) at wavelengths in the range of 193 nm to 3 micrometers (col. 3, lines 47-53) and treatment times of 0-9999 seconds (col. 4, lines 29-36).

While Whitehurst employs non-coherent light in the practice of his invention instead of coherent light (i.e., laser) due to the disadvantages listed in col. 1, lines 12-32 (e.g., high cost, size, power consumption, sophistication, etc.), it is well known in the art that coherent light may be used effectively despite its cost, size and complexity. Whether a system is more costly to purchase, takes up more space, or requires a higher skill level to operate does not negate the fact that such a system can be effective to treat skin disorders such as discussed by Whitehurst. By analogy, a diamond tipped jackhammer may be more costly to purchase and thus not recommended for use, yet such a tool would hardly be considered novel or unobvious given the known properties of diamonds. Likewise, given the known effectiveness of coherent light in treating dermatological disorders, those of ordinary skill in the art would have considered the use of a coherent light source such as a laser to be obvious for the healing of stage one and stage two wounds.

Again, regarding the treatment of stage 1-2 wounds, please refer to the examiner's arguments presented under paragraph 8 of the previous Office Action.

Regarding claim 15, similar comments made in the rejection of claim 1 apply here as well. Concerning the use of radiation with a wavelength of 930 nm, those of ordinary skill in the art would have considered the exact wavelength of operation to be an application dependent parameter. The Whitehurst invention is operative at 930 nm as cited above. The particular ailment being treated and the condition of the patient would necessarily dictate the most appropriate wavelength for the situation at hand, with routine experimentation determining the most effective treatment wavelengths for any given disease and patient type. The applicant further gives no criticality to the use of 930 nm radiation. The applicant has not disclosed that 930 nm radiation provides an advantage, is used for a particular purpose, or solves a stated problem.

4. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehurst as applied to claims 1, 2, 4, 12, 14 and 15 above, and further in view of Talmore (Pat. No. 5,344,433).

Whitehurst does not appear to explicitly discuss the average power of the radiation energy produced by the 300 W Xenon short arc lamp. Talmore, however, discloses the use of an identical light source and states that the lamp provides a light beam with an output of 1W (col. 4, lines 5-13). It would appear that the particular level of radiation power desired would depend upon the application at hand and the particular skin condition being treated. Lacking any criticality by the applicant in regards to providing a 1W output or a 5 to 10 W output, those of ordinary skill in the art would have seen the particular power level to be an obvious matter of design dependent upon the conditions of the particular wound being treated.

Response to Arguments

5. Applicant's arguments filed February 15, 2006 have been fully considered but they are not persuasive.

Regarding the rejection of claim 1 under §103 as being unpatentable over Wolff ('554), the applicant argues that a *prima facie* case of obviousness has not been established with respect to Wolff because the reference does not suggest, teach, or imply the motivation to combine or modify the reference teachings in order to produce the present invention. The examiner responds that in order to establish a prima facie case of obviousness, it is not required that the Wolff reference suggest, teach, or imply motivation to combine or modify the reference teachings. The suggestion or motivation may be found either in the references themselves, *or in the knowledge generally available to one of ordinary skill in the art* (see MPEP 706.02(j)). The suggestion or motivation will be further elaborated on below in response to applicant's Remarks.

The applicant goes on to argue that Wolff fails to suggest the desirability of using coherent radiation and optical fibers to stimulate the physical healing of stage 1 and stage 2 wounds using a 980 nm wavelength. The examiner counters that claim 1 is not restricted to the use of a 980 nm wavelength. The only recitation regarding

wavelengths refers to a range from 193 nm to 10.6 micrometers. Wolff explicitly, and by applicant's own admission (see middle of page 4 of the Remarks), discloses wavelengths that fall within this expansive range.

Regarding the use of optical fibers and the examiner's position that the use of such fibers would have been considered a matter of obvious design as set forth in the reasoned statement abridging pages 2 and 3 of the previous Office Action, the applicant states that a benefit of such use is to permit more accurate and even treatment coverage by allowing the fiber(s) to be manually moved or scanned over the wound surface in close proximity, while the radiation apparatus of Wolff is designed to broadly emit rays. The examiner responds that Wolff directly suggests that "...in many instances it is merely necessary to treat smaller parts of the body...for medical purposes (e.g., to treat psoriasis, acne and other skin irregularities or diseases," (col. 1, lines 49-53). The use of fiber optics to convey radiation precisely to very limited areas of the body is clearly knowledge that was generally available to one of ordinary skill in the art at the time of the invention. The applicant certainly is not the first to discover that optical fibers may be used to precisely and accurately treat dermatological conditions (contrary to the applicant's contention, the Neuberger '205 patent is available as prior art). Given the general teaching by Wolff to use non-ablative radiation of a wavelength included in the claimed range to treat stage 1 and stage 2 wounds and the teaching of Wolff to tailor the radiation application to the size of the wound in addition to the knowledge generally available to one of ordinary skill in the art, artisans would have clearly recognized the obviousness of using optical fibers to convey the radiation to the wound if the wound for the individual under treatment was limited to an even smaller portion of the body than that discussed in exemplary fashion by Wolff (e.g., a small patch of skin on the nose or a single facial wart or pimple as opposed to the entire face).

Concerning the use of coherent vs. non-coherent radiation, the applicant states that the determination of whether non-coherent energy is appropriate or not is not an issue because this subject matter was deleted from claim 1. Merely because the applicant chose to delete this limitation from claim 1 in an obvious attempt to avoid succumbing to the art rejection, does not eliminate the evidence that coherent and non-

coherent radiation are equivalents in the context of this invention. As such, one of ordinary skill in the art would have expected the applicant's invention to work equally well with either radiation source (see page 6, lines 7 and 8 of the present specification). Such a finding supports the examiner's reasoned statement in the prior Office Action under paragraph 3 (see Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Int. 1985).

The applicant additionally argues against the examiner's assertion that the healing process is not dependent upon the particular means used to transmit the radiation to the wound. It is stated that if this were so, one could just sit outside in the sun (see page 3, par. 5 of the Rejection mailed August 5, 2004) or under a sun lamp or arc lamp (see page 6, lines 7 and 8 of the present specification), but "...in order to achieve the appropriate energy levels and densities at the wound, an optical fiber is used," (Remarks page 5, third full paragraph). Once again the examiner cannot find in claim 1 any recitation limiting the energy level and energy density applied to the wound. The examiner cannot read additional limitations into claim 1 that are not explicitly present. Furthermore, if one could only obtain the appropriate energy levels and energy densities by employing an optical fiber as argued by applicant, it is unclear why the applicant's own disclosure directly contradicts this assertion by explicitly teaching that one may use either coherent radiation "...such as a laser beam, or non-coherent, *such as radiation emitted from a lamp* [emphasis added]," (page 6, lines 7 and 8).

The applicant's argument that Talmore does not use an optical fiber *per se* but rather a light guide is insufficient. The examiner can find no disclosure of fiber size by the applicant. It is further noted that the applicant incorrectly states in this section of the Remarks that the '205 patent owned by the same assignee as the present invention cannot be used in a §103 rejection based on common ownership. The '205 patent to the contrary is available as prior art under §102(a) and §102(e), as well as §103/102(a) and §103/102(e) (note publication date, different inventive entity, and lack of proper common ownership statement).

Regarding the treatment of stage 1 and stage 2 wounds, the applicant argues that while it would be obvious to try to treat such wounds to prevent progression into the

later stages, the issue is not the desire, but rather the effectiveness of such treatment. The examiner disagrees. In determining obviousness, if the prior art suggests such treatment, the relative effectiveness of the treatment is immaterial. While not conceding the effectiveness of the modified Wolff device, the applicant has not made the case that the use of more severe or aggressive therapy would be unable to prevent progression of the wound to stage 3 or stage 4. In any event, one of ordinary skill in the art would expect the effectiveness of treatment with the Wolff device as modified above to be substantially equivalent to that of the present invention.

Regarding the rejection of claim 2, the applicant states that the Wolff reference does not disclose power densities of at least 1 W/cm^2. The examiner never stated that Wolff explicitly did. Rather the examiner presented a logical argument for why one would consider such magnitudes to be present for the treatment of similar wounds. The applicant has not addressed this reasoning.

Again regarding claim 2, the applicant turns to a discussion of wavelengths when such limitations are not present in the claim.

Regarding the rejection of claim 12, the applicant is correct in assuming that ultraviolet light helps to eliminate bacteria as is old and well-known.

Regarding the use of a 980 nm laser and associated claims, the applicant refers to page 3, lines 14 to 19 (sic)(the examiner will assume it was the applicant's intent to refer to lines 9-13 on page 3 of the specification). It is unclear why the applicant is referring to a patent that the applicant adamantly argues is not directed to the treatment of stage 1 and stage 2 wounds for a showing of criticality in the treatment of stage 1 and stage 2 wounds with such a wavelength. Nonetheless, the base claim which the applicant apparently considers patentable on its own does not limit the device to such a limited wavelength. The evidence clearly suggests that a large range of wavelengths would be equally effective in the treatment of stage 1 and stage 2 wounds. The examiner questions the applicant as to whether he/she would consider a competitor producing a substantially similar device operating within the 193 nm to 10.6 micrometer range but not at 980 nm to be infringing on any patent based on a claim directed to 980 nm radiation.

Similar reasoning applies to the application of the Whitehurst reference to claims 1, 2, 4, 12, 14 and 15 and will not be repeated for the sake of brevity.

It is noted that the applicant refers to "new" claim 15, but this claim was previously presented and treated in the last Office Action.

The applicant additionally argues that the examiner has not made it known why one of ordinary skill in the art would have considered a coherent light source to be obvious for the treatment of stage 1 and stage 2 wounds. The examiner has set forth a logical statement of reasoning on page 4, par. 3 of the prior Office Action to explain why one of ordinary skill would consider such a modification obvious. Note also the comments made above.

Regarding the rejection of claims 9 and 10, the applicant again discusses the use of 980 nm wavelengths, but this limitation is not present in either of these claims. Any adjustment to output power to account for the different radiation would have been considered a matter of routine experimentation and based upon the actual ailment and individual being treated. Again note related comments above.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on M-F at 571 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
May 14, 2006

KENNEDY SCHAETZLE
PRIMARY EXAMINER